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EXAMINER	
KAROL, JODY LYNN	
ART UNIT	PAPER NUMBER
1617	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,460	MICHEL, OLAF	
	Examiner	Art Unit	
	Jody L. Karol	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *8-10 and 26-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 11-25* is/are rejected.

7)☒ Claim(s) *3* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/22/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to the Response to Election/Restriction filed on 12/18/2008. Claims 1-30 are pending.

Election/Restrictions

1. Applicant's election **with** traverse of Group I, claims 1-25, directed to sticks for topical or transmucosal application of a skin care or active agent onto and via the nasal mucosal and the species election **without** traverse of atropine as the active agent in the replies filed on 7/11/2008 and 12/18/2008 is acknowledged.

The traversal is on the ground(s) that there would not be a serious search and examination burden to examine all the claims together. This is not found persuasive because restriction in accordance with the rules of unity of invention is considered proper when the common technical feature among the groups is not a special technical feature because it does not make a contribution over the prior art.

As stated in the 6/12/2008 Requirement for Restriction/Election, the common technical feature among the groups is a stick for the topical or transmucosal application of a skin care or active agent onto and via the nasal mucosa. The nasal stick cannot be considered a special technical feature because it is known in the prior art. For example, Weintraub et al. (US 5,318,961) teaches aminosteroid compositions that can be applied to the nasal mucosa for topical administration, and can be employed via applicator sticks for carrying the formulation (see abstract and column 7, lines 27-32). Accordingly, no special technical feature exists, and the unity of invention is considered

to be lacking.

The restriction requirement in accordance with the rules of unity of invention is still deemed proper and is therefore made FINAL.

Claims 8-10 and 26-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Accordingly, claims 1-7 and 11-25 are examined on the merits herein, and prior art is applied in so much as it reads on the elected species.

Priority

2. This Application is a 371 of PCT/EP03/12150 International Filing Date: 10/31/2003, which claims priority to Application No. 102 50 944.1 filed in Germany on 10/31/2002.

Information Disclosure Statement

3. The information disclosure statement (IDS) filed on 4/22/2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered.

Claim Objections

4. Claim 3 is objected to because of the following informalities: carnauba wax is misspelled as “carnauba was” in line 4 of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 11-12, 14, 17, 21-22, and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 4, the recitation of "essentially contains" is indefinite because it is unclear what components are included/excluded from the composition. It is not clear if "consisting essentially of " is intended to limit the ingredients therein? However, for examination purposes, and in the interest of compact prosecution, "essentially contains" will be interpreted as “comprising.”

In regards to claim 11, the phrase "for example" or “(i.e. in the form of filled nanoparticles)” renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 12 recites the limitation "wherein the nanoparticles”" in lines 1. There is insufficient antecedent basis for this limitation in the claim because it is unclear if claim 11 contains said limitation (see 112, 2nd paragraph rejection *supra*). Further, the recitation of “at least one of the above mentioned skin care and/or active agents” is indefinite because it is unclear as to which skin care and/or active agents the claim is referring.

In regards to claim 14, the recitation of "which contains photoprotective agents" is indefinite because it is unclear if the photoprotective agents **are** the active agent, or if they are present in the stick **in addition** to the active agent. For examination purposes and in the interest of compact prosecution, the photoprotective agents will be considered as an additional ingredient aside from the active agent atropine.

Claim 17 recites the limitation "drive device" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claims 21-22 and 24 recite the limitation "sleeve" in line 1 of each claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-7, 11-12, 13, 19, and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Georgitis ("Nasal Atropine Sulfate: Efficacy and Safety of 0.050% and 0.075% Solutions for Severe Rhinorrhea," *Arch. Otolaryngol. Head Neck Surg.*, August 1998, vol. 124, pgs 916-920) in view of McGinity et al. (US 5,622,933).

The instant claims are directed to sticks for topical or transmucosal application of the active agent via the nasal mucosa, wherein the stick material contains a composition of at least on carrier substance and at least the active agent atropine.

Georgitis teaches atropine sulfate, 50 or 75 µg given 4 times daily as a nasal spray is effective in reducing rhinorrhea and post nasal drip in patients with perennial allergic rhinitis (see abstract; page 919, right column).

Georgitis does not teach a stick for topical or transmucosal application of atropine.

McGinity et al. teach stick formulations for the topical delivery of water soluble and/or water soluble agents for the delivery of therapeutic agents to the skin or mucosal surfaces of the body (see abstract; column 1, lines 12-17). McGinity et al. further teach that conventional formulations such as ointments or aerosols are wasteful because of difficulty in delivery of a precise amount of said formulation to a specific area (see column 1, lines 19-35). The stick formulations have ease of delivery, good spreadability, not easily washed from the skin, and maintain solid state at room temperature while maintaining good physical and chemical stability of the incorporate drug (see column 2, lines 55-22). Suitable carrier components include waxes, oils, water, and surfactants, as claimed in the instant claims 2-3, wherein the active agent is

at least partially dissolved in water droplets (i.e. fluid) are dispersed in the wax matrix of the stick as claimed in the instant claims 11-12 (see column 1, lines 24-35). McGinity et al. also teach additional agents such as preservatives such as methyl paraben or propyl paraben, or antioxidants such as BHT and BHA may be added to the stick formulations as claimed in the instant claims 5 and 13 (see column 4, lines 26-32). McGinity et al. also teach that the stick formulation may also comprise a semi-solid vehicle, preferably cocoa butter as claimed in the instant claim 4, in ordered to improve the aesthetic feel of the stick, and to improve spreadability (see column 7, lines 35).

It would have been obvious to one of ordinary skill in the art at the time of the invention to formulate a stick for mucosal application as taught by McGinity et al. using the atropine taught by Georgitis. One of ordinary skill in the art would have motivated to formulate atropine into a stick application to the nasal mucosa for the treatment of perennial allergic rhinitis and for ease of delivery. One of ordinary skill in the art would have had a reasonable expectation of success in employing atropine in a stick form because Georgitis teaches atropine sulfate in a nasal spray, while McGinity et al. teach stick formulations for both water soluble and insoluble drugs, and for application to mucosal surfaces. Thus, it is expected that a stick formulation comprises atropine or atropine sulfate could be formulated for nasal mucosal application.

In regards to claim 12, while the prior art references do not explicitly teach "nanoparticles" containing the active agent, McGinity et al. teach water droplets dispersed within the wax matrix wherein the therapeutic agent is at least partially dissolved in said water droplets. The optimization of the size of the water droplets is

considered to be within the purview of the ordinary artisan, absent a showing of criticality of the claimed particle dimensions.

In regards to claim 19, it is noted that the intended use of "suitable for delivering skin care or active agents to the vestibulum nasi" is not given patentable weight. However, it is expected since the stick is applied to the nasal mucosal, the active agent will be delivered to the vestibulum nasi (anterior part of the nasal cavity).

In regards to claims 22-24, it is noted that the decorations, product information, and consumer information are not given patentable weight. Where the only difference between a prior art product and a claimed product is printed matter that is not functionally related to the product, the content of the printed matter will not distinguish the claimed product from the prior art. *In re Ngai*, 367 F.3d 1336, 1339, 70 USPQ2d 1862, 1864 (Fed. Cir. 2004). Thus, since the printed matter of claims 22-24 is not functionally related to stick product, its content does not distinguish it form the prior art.

Thus, the invention as a whole would have been *prima facie* obvious to one of ordinary skill the art.

8. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Georgitis ("Nasal Atropine Sulfate: Efficacy and Safety of 0.050% and 0.075% Solutions for Severe Rhinorrhea," *Arch. Otolaryngol. Head Neck Surg.*, August 1998, vol. 124, pgs 916-920) in view of McGinity et al. (US 5,622,933) as applied to claims 1-7, 11-13, 19, and 22-24 above, and further in view of Deckner et al. (US 4,919,934).

Claim 14 (as best understood, see 112, 2nd paragraph rejection above) is directed to nasal sticks wherein the stick additionally comprises a photoprotective agent.

Georgitis and McGinity et al. are described *supra* as applied to claims 1-7, 11-13, 19, and 22-24.

Georgitis and McGinity et al. do not teach sticks that additionally comprise a photoprotective agent.

Deckner et al. teach wax based cosmetic sticks comprising sunscreen agents (see abstract). Deckner et al. further teach a wide variety of acceptable conventional sunscreening agents, wherein products with SPF values of 2-50 are commercially available (see column 4, line 4 to column 5, lines 56).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add a sunscreen agent as taught by Deckner et al. to the nasal stick obvious over Georgitis in view of McGinity et al. One of ordinary skill in the art would have been motivated to add a sunscreen to the nasal stick in order to provide SPF protection to the stick and to the skin/mucosa areas wherein the stick is applied. One of ordinary skill in the art would have had a reasonable expectation of success in doing so because Deckner et al. teach sunscreen actives can be added to wax-based sticks, and the stick taught by McGinity et al. is also a wax based stick composition.

Thus, the invention as a whole would have been *prima facie* obvious to one of ordinary skill the art.

9. Claims 15-18, 21, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Georgitis ("Nasal Atropine Sulfate: Efficacy and Safety of 0.050% and 0.075% Solutions for Severe Rhinorrhea," *Arch. Otolaryngol. Head Neck Surg.*, August 1998, vol. 124, pgs 916-920) in view of McGinity et al. (US 5,622,933) as applied to claims 1-7, 11-13, 19, and 22-24 above, and further in view of Lepsius et al. (US 5,567,071).

The instant claim 15-18, 21, and 25 are directed to sticks of cylindrical shape (claim 15), sticks with a base connected to the stick material and a sleeve surrounding said material (claim 16), that has a driving device for moving the stick material in and out that is provided as a moulded device in one piece together with the sleeve and base (claim 17), wherein said sleeve is provided with a stick material using a refill cartridge (claim 18), wherein the stick and sleeve have a size of about 0.5 to 2 cm (claim 21), and wherein the stick is provided in a package that opens at the base of the stick (claim 25).

Georgitis and McGinity et al. are described *supra* as applied to claims 1-7, 11-13, 19, and 22-24.

Georgitis and McGinity et al. do not teach sticks of cylindrical shape (claim 15), sticks with a base connected to the stick material and a sleeve surrounding said material (claim 16), that has a driving device for moving the stick material in and out that is provided as a moulded device in one piece together with the sleeve and base (claim 17), wherein said sleeve is provided with a stick material using a refill cartridge (claim 18), wherein the stick and sleeve have a size of about 0.5 to 2 cm (claim 21), or wherein the stick is provided in a package that opens at the base of the stick (claim 25).

Lepsius et al. teach refill cartridges for stick product dispenser include lipsticks, release agent sticks, etc. (i.e. sticks for topical use) that are provided by molding the stick product material to have a shape substantially the same internal shape of the associated dispenser casing or holding (i.e. sleeve), wherein the dispenser comprises a base with a driving device for moving the stick (see diagram) as claimed in the instant claims 16-18 (see abstract; diagram). As demonstrated by Figure 2, the stick is cylindrical as claimed in the instant claim 15 (see Drawings, sheet 1, Figure 2).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the stick dispenser and refill cartridge as taught by Lepsius et al. with the nasal stick obvious over Georgitis in view of McGinity et al. One of ordinary skill in the art would have been motivated to use the stick dispenser and refill cartridge in order to provide a convenient means for dispensing the nasal stick obvious over Georgitis in view of McGinity et al. One of ordinary skill in the art would have had a reasonable expectation of success using the stick dispenser and refill cartridge taught by Lepsius et al. with the nasal stick obvious over Georgitis in view of McGinity et al. because Lepsius et al. teach said dispensers and refill cartridges are used for sticks, such as sticks for topical use.

In regards to claim 21, the optimization of the size of the stick and sleeve (and thus the dispenser) for its intended use of application within the nasal cavity is within the purview of the ordinary artisan.

In regards to claim 25, it would have been obvious to one of ordinary skill in the art at the time of the invention to package the stick material for commercial distribution.

One of ordinary skill in the art would have been motivated to package the stick so that it is protected during transport, before consumer purchase and use. Further, it is obvious to have the package open at the base of the stick, so that the stick portion to be applied to the nasal mucosa is not touched and/or contaminated by handling.

Thus, the invention as a whole would have been *prima facie* obvious to one of ordinary skill the art.

10. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Georgitis ("Nasal Atropine Sulfate: Efficacy and Safety of 0.050% and 0.075% Solutions for Severe Rhinorrhea," *Arch. Otolaryngol. Head Neck Surg.*, August 1998, vol. 124, pgs 916-920) in view of McGinity et al. (US 5,622,933) as applied to claims 1-7, 11-13, 19, and 22-24 above, and further in view of Stuhr (DE 199 54 004 A1 – Derwent abstract and diagram only).

Claim 20 is directed to a stick wherein the upper end of the stick material is shaped to allow a precise punctiform or lineshaped application of said agents on the vestibulum nasi (anterior of nasal cavity).

Georgitis and McGinity et al. are described *supra* as applied to claims 1-7, 11-13, 19, and 22-24.

Georgitis and McGinity et al. do not teach a stick wherein the upper end of the stick material is shaped to allow a precise punctiform or lineshaped application of said agents on the vestibulum nasi (anterior of nasal cavity).

Stuhr teaches a block shaped stick for use as a lipstick, etc. (i.e. topical use) that is shaped like a double concave lens so that the material can be applied as a line, etc. (see Derwent abstract; diagram).

It would have been obvious to one of ordinary skill in the art at the time of the invention to formulate a block shaped stick that is shaped like a double concave lens as taught by Stuhr using the nasal stick obvious over Georgitis in view of McGinity et al. One of ordinary skill in the art would have been motivated to adjust the shape of the stick in order to apply the material in a line, so that the material is only applied to the effective area, reducing side effects and waste of the material. One of ordinary skill in the art would have had a reasonable expectation of success in adjusting the shape of the nasal stick obvious over Georgitis in view of McGinity et al. because Stuhr teaches the concave stick is used for topical applications.

Thus, the invention as a whole would have been *prima facie* obvious to one of ordinary skill the art.

Conclusion

No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jody L. Karol whose telephone number is (571)270-3283. The examiner can normally be reached on 8:30 am - 5:00 pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

JLK

/JENNIFER M KIM/
Primary Examiner, Art Unit 1617